In the United States Court of Federal Claims

OFFICE OF SPECIAL MASTERS

No. 20-0020V

UNPUBLISHED

KEVIN HARRIS, Petitioner, v. SECRETARY OF HEALTH AND HUMAN SERVICES, Respondent.	Chief Special Master Corcoran Filed: December 2, 2021 Special Processing Unit (SPU); Table Injury Dismissal; Influenza (Flu); Shoulder Injury Related to Vaccine Administration (SIRVA); Prior Shoulder Pain; Rotator Cuff Tear.

Amy A. Senerth, Muller Brazil, LLP, Dresher, PA, for Petitioner.

Madelyn E. Weeks, U.S. Department of Justice, Washington, DC, for Respondent.

FINDINGS OF FACT AND CONCLUSIONS OF LAW DISMISSING TABLE CLAIM[1]

On January 8, 2020, Kevin Harris filed a petition for compensation in the National Vaccine Injury Compensation Program, 42 U.S.C. §300aa-10, *et seq.*[2] (the "Vaccine Act"). Petitioner alleges that as a result of receiving an influenza ("flu") vaccine on September 11, 2018, he suffered a right shoulder injury related to vaccination ("SIRVA") as defined on the Vaccine Injury Table (the "Table"). Petition (ECF No. 1) at Preamble. The case was assigned to the Special Processing Unit ("SPU") of the Office of Special Masters.

[1] Because this unpublished opinion contains a reasoned explanation for the action in this case, I am required to post it on the United States Court of Federal Claims' website in accordance with the E-Government Act of 2002. 44 U.S.C. § 3501 note (2012) (Federal Management and Promotion of Electronic Government Services). **This means the opinion will be available to anyone with access to the internet.** In accordance with Vaccine Rule 18(b), petitioner has 14 days to identify and move to redact medical or other information, the disclosure of which would constitute an unwarranted invasion of privacy. If, upon review, I agree that the identified material fits within this definition, I will redact such material from public access.

[2] National Childhood Vaccine Injury Act of 1986, Pub. L. No. 99-660, 100 Stat. 3755. Hereinafter, for ease of citation, all section references to the Vaccine Act will be to the pertinent subparagraph of 42 U.S.C. § 300aa (2012).

For the reasons discussed below, a preponderance of the evidence supports the conclusion that Petitioner was experiencing pain in his right shoulder approximately *one month before* receiving the flu vaccine – meaning he cannot establish Table onset for his Table SIRVA claim, and therefore the Table claim must be dismissed. Nonetheless, Petitioner will be afforded the opportunity to pursue a non-Table claim (to which Respondent may likewise respond) following transfer out of the SPU.

I. Relevant Procedural History

As noted above, the claim was filed and the records were deemed to be substantially complete in early 2020. ECF Nos. 1, 11-12. On March 28, 2021, Respondent filed his report pursuant to Vaccine Rule 4(c), in which he asserted that Petitioner could not establish that his onset of shoulder pain occurred within 48 hours after vaccination. Rather, Petitioner had endorsed left shoulder pain at two chiropractic appointments in the prior month. Respondent also noted that Petitioner initially attributed his pain to weight training, and that he had a "long orthopedic history" including a left shoulder injury leading to a surgical repair of a labral tear in 2009, which may have caused or contributed to the post-vaccine findings on MRI and repeat surgery. Resp. Report (ECF No. 26) at 5-6.

On June 24, 2021, I ordered Petitioner to show cause why his claim should not be dismissed for the aforementioned reasons. Show Cause Order (ECF No. 27). Petitioner filed his brief on August 24, 2021 (ECF No. 29). Respondent filed a response on September 23, 2021 (ECF No. 30). Petitioner did not file a reply. Therefore, this matter is now ripe for adjudication.

II. Issue

At issue is whether Petitioner experienced the new onset of shoulder pain within 48 hours after his September 11, 2018 vaccination, as required for a Table SIRVA injury based upon the relevant Qualifications and Aids to Interpretation ("QAI"). 42 C.F.R. § 100.3(c)(10)(ii).

III. Authority

Pursuant to Vaccine Act § 13(a)(1)(A), a petitioner must prove, by a preponderance of the evidence, the matters required in the petition by Vaccine Act § 11(c)(1). A special master must consider, but is not bound by, any diagnosis, conclusion, judgment, test result, report, or summary concerning the nature, causation, and aggravation of petitioner's injury or illness that is contained in a medical record. Section 13(b)(1). "Medical records, in general, warrant consideration as trustworthy

evidence. The records contain information supplied to or by health professionals to facilitate diagnosis and treatment of medical conditions. With proper treatment hanging in the balance, accuracy has an extra premium. These records are also generally contemporaneous to the medical events." *Cucuras v. Sec'y of Health & Human Servs*., 993 F.2d 1525, 1528 (Fed. Cir. 1993).

Accordingly, where medical records are clear, consistent, and complete, they should be afforded substantial weight. *Lowrie v. Sec'y of Health & Human Servs*., No. 03-1585V, 2005 WL 6117475, at *20 (Fed. Cl. Spec. Mstr. Dec. 12, 2005). However, this rule does not always apply. In *Lowrie*, the special master wrote that "written records which are, themselves, inconsistent, should be accorded less deference than those which are internally consistent." *Lowrie*, at *19.

Nevertheless, it is also the case that "medical records may be incomplete or inaccurate." *Camery v. Sec'y of Health & Human Servs*., 42 Fed. Cl. 381, 391 (1998). The Court of Federal Claims later outlined four possible explanations for inconsistencies between contemporaneously created medical records and later testimony: (1) a person's failure to recount to the medical professional everything that happened during the relevant time period; (2) the medical professional's failure to document everything reported to her or him; (3) a person's faulty recollection of the events when presenting testimony; or (4) a person's purposeful recounting of symptoms that did not exist. *La Londe v. Sec'y of Health & Human Servs*., 110 Fed. Cl. 184, 203-04 (2013), *aff'd*, 746 F.3d 1335 (Fed. Cir. 2014).

The Court has also said that medical records may be outweighed by testimony given later in time that is "consistent, clear, cogent, and compelling." *Camery*, 42 Fed. Cl. at 391 (citing *Blutstein v. Sec'y of Health & Human Servs*., No. 90-2808, 1998 WL 408611, at *5 (Fed. Cl. Spec. Mstr. June 30, 1998). The credibility of the individual offering such testimony must also be determined. *Andreu v. Sec'y of Health & Human Servs.*, 569 F.3d 1367, 1379 (Fed. Cir. 2009); *Bradley v. Sec'y of Health & Human Servs*., 991 F.2d 1570, 1575 (Fed. Cir. 1993). And the Federal Circuit recently "reject[ed] as incorrect the presumption that medical records are accurate and complete as to all the patient's physical conditions." *Kirby v. Sec'y of Health & Human Servs*., 997 F.3d 1378, 1383 (Fed. Cir. 2021).

The special master is obligated to fully consider and compare the medical records, testimony, and all other "relevant and reliable evidence contained in the record." *La Londe*, 110 Fed. Cl. at 204 (citing § 12(d)(3); Vaccine Rule 8); *see also Burns v. Sec'y of Health & Human Servs*., 3 F.3d 415, 417 (Fed. Cir. 1993) (holding that it is within the special master's discretion to determine whether to afford greater weight to medical

records or to other evidence, such as oral testimony surrounding the events in question that was given at a later date, provided that such determination is rational).

A special master may find that the first symptom or manifestation of onset of an injury occurred "within the time period described in the Vaccine Injury Table even though the occurrence of such symptom or manifestation was not recorded or was incorrectly recorded as having occurred outside such period." Section 13(b)(2). "Such a finding may be made only upon demonstration by a preponderance of the evidence that the onset [of the injury] . . . did in fact occur within the time period described in the Vaccine Injury Table." *Id*.

IV. Relevant Factual Evidence

I have reviewed all of the records filed to date. This ruling, however, is limited to determining facts pertaining to the onset of Petitioner's shoulder pain in 2018. Accordingly, I will only summarize or discuss evidence that directly pertains to this issue.

- Petitioner was born in 1967. The medical records reflect that at the relevant time, he was employed as a schoolteacher and track coach, and resided with his wife in Oklahoma. He is right-hand dominant.

- Over nine years before the subject vaccination, on August 4, 2009, Petitioner presented to orthopedic surgeon Jimmy Conway Jr., M.D., seeking treatment for left shoulder pain and weakness since falling off his mountain bike two weeks earlier. Dr. Conway's initial assessment was a SLAP tear.[3] Ex. 8 at 6.

- On August 24, 2009, an MRI visualized potential tears in the labrum as well as the supraspinatus tendon.[4] Ex. 8 at 6-8, 9.

- On August 31, 2009, Dr. Conway undertook arthroscopic surgery. He performed an "extensive bursectomy" and "excellent repairs" of tears of the anterior and superior labrum. Ex. 8 at 12-13. However, Dr. Conway failed to identify "any significant problem with the rotator cuff on the underneath surface… or the bursal surface," or any "significant subacromial spur." *Id.* at 14.

[3] SLAP stands for "superior labrum from anterior to posterior." The labrum is the "attachment site for the shoulder ligaments and supports the ball-and-socket joint as well as the rotator cuff tendons and muscles." Stephen Fealey, M.D., *Shoulder Labrum Tears: An Overview*, Hospital for Special Surgery, https://www.hss.edu/conditions_shoulder-labrum-tears-overview.asp (last accessed October 29, 2021).

[4] The supraspinatus, infraspinatus, teres minor, and subscapularis tendons form the rotator cuff. *Dorland's Illustrated Medical Dictionary* (33 ed. 2019), https://www.dorlandsonline.com (hereafter "*Dorland's*").

- On September 29, 2009, Dr. Conway summarized that Petitioner had undergone an "anterior capsulolabral reconstruction" and "superior labral repair." Ex. 8 at 15. After one incident in which a "kid ran into his shoulder causing immediate pain and popping initially," he was "doing great." *Id.* at 15-16.

- On December 10, 2009, Dr. Conway recorded that Petitioner's left shoulder had "no pain, some soreness." *Id.* at 31.

- On December 23, 2009, upon Petitioner's discharge from physical therapy, his left shoulder pain level ranged from 0 – 2 out of 10. Ex. 9 at 51. He had achieved 90% of his goals, but still had "slightly limited" range of motion and reduced strength (5-/5) on forward flexion. *Id.* He would perform home exercises focused on additional pain relief, range of motion, and muscle function. *Id.*

- The subsequent medical records do not address the *left* shoulder again until January 29, 2015, when Petitioner was recorded to have *bilateral* full range of motion and "good" strength on the right but only "satisfactory" strength on the left. Ex. 8 at 53.[5]

- On May 23, 2017, Petitioner established care at a new primary care practice. There were no complaints or abnormal findings at the left shoulder. He was "overall very healthy" and reported working out regularly in addition to his employment as a schoolteacher and track coach. Ex. 10 at 1-4; *see also id.* at 5-45 (subsequent primary care and urgent care encounters).

- On July 24, 2018, Petitioner began seeing a chiropractor for the treatment of "chronic, severe pain" in his right leg. Ex. 2 at 1. At each chiropractic appointment, Petitioner hand-wrote his own assessment of his health status, affected areas of the body, and corresponding pain rated from 0 – 10. The chiropractor then completed a separate record of treatment. *See, e.g.*, Ex. 2 at 6-7.[6]

- For approximately the first month, Petitioner and his chiropractor focused on his right leg pain. Ex. 2 at 6-22. Then on August 27, 2018, Petitioner newly endorsed pain in his left shoulder and upper to mid-back. *Id.* at 45. He rated this pain at 4-5/10. *Id.* But it is not addressed in the chiropractor's record. *Id.* at 46.
- In the records from the next encounter, on August 30, 2018, Petitioner and the chiropractor address only his right leg. Ex. 2 at 43-44.

[5] This appointment focused on assessing Petitioner's recovery after surgery on his *right* shoulder in late 2015. I have reviewed the relevant records, but I find them insignificant towards resolving the onset of Petitioner's *left* shoulder pain in 2018.

[6] Respondent correctly referred to the chiropractor's records as SOAP notes. SOAP is a format for medical records. "*S* indicates subjective data obtained from the patient and others close to him; *O* designates objective data obtained by observation, physical examination, diagnostic studies, etc.; *A* refers to assessment of the patient's status through analysis of the problem, possible interaction of the problems, and changes in the status of the problems; *P* designates the plan for patient care." *Dorland's.*

- On September 4, 2018, Petitioner reported left shoulder pain of 6-7/10. Ex. 2 at 41. But again, the chiropractor did not address this complaint. *Id.* at 42.[7]

- On September 7, 2018, Petitioner and the chiropractor addressed only his right leg. Ex. 2 at 39-40.

- On September 11, 2018, Petitioner received the flu vaccine in his left arm, in the context of his employment. Ex. 1 at 2; Ex. 3 at 12.[8]

- Six days later, on September 14, 2018, Petitioner returned to his chiropractor, reporting left shoulder pain of 6-7/10. Ex. 2 at 37. But again, the chiropractor did not address this complaint. *Id.* at 38.

- At the next appointment on September 21, 2018, the chiropractor undertook a "shoulder regional examination." Ex. 2 at 24. Petitioner reported left shoulder pain and weakness "due to weightlifting." *Id.* On physical exam, the shoulder was rounded on rotation of the scapula and humerus, and tender at multiple areas on painful palpation. *Id.* Range of motion was abnormal and painful. *Id.* The chiropractor checked off findings corresponding to impingement, biceps tendonitis, and labral tear. *Id.*; *see also id.* at 35 (Petitioner's form on that date, reporting a "new complaint" of "left shoulder impingement" rated at 8 out of 10).

- On September 21, 2018, and on subsequent dates, the chiropractor treated Petitioner for a left rotator cuff tear. Ex. 2 at 26, 28, 30, 32, 34, 36.

- On October 1, 2018, Petitioner's wife contacted their primary care practice, reporting his pain since receiving a flu vaccine "@ school 2 wks ago." Ex. 3 at 12.[9]

- On October 2, 2018, Petitioner presented to the primary care practice. He reported that after receiving the flu shot at school on September 11, 2018, he developed left shoulder pain and a "small knot." *Id.* at 8. Petitioner reported that he had seen his chiropractor "3 times." *Id.*[10]

- Later on October 2, 2018, at the Onecore Orthopedics practice, a physician assistant ("PA") recorded that Petitioner had left shoulder pain with a "gradual and insidious onset," "present for 2 weeks," and currently rated at 8 out of 10. Ex. 4 at 11. The PA's tentative impression was that Petitioner was suffering from a partial

[7] Petitioner "requested billing records from Sports Medicine to verify that there was in fact an appointment on September 4, 2018." Brief at n. 1. The billing records indicate that there was. Ex. 14 at 2.

[8] This case does not involve a workers' compensation claim. Status Report filed May 18, 2020 (ECF No. 17).

[9] The vaccine was in fact 20 days (just shy of 3 weeks) before this date.

[10] While Petitioner only saw the chiropractor three times after the vaccination, he had multiple appointments beforehand, including two appointments where he endorsed left shoulder pain.

incomplete rotator cuff tear, for which he administered a steroid injection and prescribed Mobic. *Id.*; *see also* Ex. 8 at 8-9 (follow up appointment).

- On December 4, 2018, Petitioner sought a second opinion at McBride Orthopedic Hospital. A PA took down the history including "left shoulder labral repair and possible rotator cuff repair by Dr. Conway in April 2010." Ex. 5 at 146; *see also id.* at 150.[11] Petitioner reported that he had done well postoperatively, then experienced new left shoulder pain beginning in mid-September 2018, at work. *Id.* at 146, 149. Petitioner could not "recall any specific injury or trauma" and reported a "gradual increase" in pain. *Id.* at 146. The PA obtained and reviewed imaging, then recorded an impression of left shoulder pain with impingement, "AC DJD" [acromioclavicular joint degenerative joint disease], rotator cuff tendonitis versus tear, and possible labral tear. *Id.* at 147.

- On December 18, 2018, an orthopedist, Robert A. German, M.D., concurred that the MRI of Petitioner's left shoulder suggested "a large rotator cuff tear involving the entire supraspinatus extending into the infraspinatus." Ex. 5 at 148. Dr. German added: "There are some changes around the labrum likely related to his previous procedure, but the lion share of his problems are related to this rotator cuff injury." *Id.* Dr. German and Petitioner agreed to proceed with corrective surgery. *Id.*

- Upon undertaking the surgery on December 26, 2018, Dr. German recorded that the indication included: "several-year history of increasing left shoulder pain." Ex. 5 at 189. Dr. German first observed that at the site of the previous surgery, there was "suture material and instability of the biceps anchor." *Id.* He "removed the suture material… used arthroscopic scissors to release the biceps tendon… [and] debrided the torn labral tissue back to stable tissue." *Id.* Dr. German then moved to the rotator cuff, where he repaired a full-thickness tear "extending from the rotator interval back into the infraspinatus with a split between the supa- and infraspinatus." *Id.*

- On February 14, 2019,[12] upon beginning a post-operative course of physical therapy ("PT"), Petitioner recounted that he had received "a flu shot in the middle of the month and he had pain associated with that. Was wondering if the shot had gotten in the bursa or something. Had gone to the chiropractor for his knee and asked him [the chiropractor] to do something with his shoulder, and the chiropractor referred him to another doctor." Ex. 6 at 2.[13] He underwent fifteen (15) PT sessions and was discharged on April 1, 2019. *See generally* Ex. 6.

[11] *But see* Ex. 8 at 12-15 (reflecting that the surgery did not address the rotator cuff, and actually took place in August 2009).

[12] Respondent says the initial PT appointment was on February 2, 2019. Rule 4(c) Report at 3. But the medical record says February 14, 2019.

[13] This chronology omits Petitioner's reports to his chiropractor, of pain in and around his shoulder, prior to the vaccination.

- On April 23, 2019, Dr. German summarized that Petitioner had suffered a "massive tear," and the surgery had consisted of "a four anchor repair as well as a biceps tenodesis." Ex. 5 at 193. Petitioner had achieved a good recovery and was following with a home exercise program. *Id.* at 193-96.

- In his affidavit (dated January 3, 2020), Petitioner recalls that he underwent surgery on his left shoulder, followed by a course of physical therapy which ended on December 23, 2009. Ex. 12 at ¶¶ 3-4. He avers: "On September 11, 2018, I was completely recovered from my prior injury had no left shoulder pain." *Id.* at ¶ 5. He states: "Following vaccination on September 11, 2018, I felt left shoulder soreness and weakness. By September 15, 2018, I felt sharp left shoulder pain." Ex. 12 at ¶ 6. However, he does not address the August 22, and September 4, 2018, records, in which he reported shoulder pain to his chiropractor.

V. Parties' Arguments

Petitioner contends that his left shoulder had recovered completely after the 2009 surgery. He also does not deny his own contemporaneous reports of left shoulder pain on two occasions before the vaccine, but emphasizes the fact that his chiropractor did not record any left shoulder symptoms or treatment on those same dates. *Id.* [14]

Respondent argues that weight should be afforded to Petitioner's reports of pre-vaccination shoulder pain despite his chiropractor's failure to record or treat those complaints. Response at 1-2. Respondent adds that Petitioner did not consistently report that his pain began after the vaccination. *Id.* (citing Ex. 2 at 24; Ex. 4 at 11; Ex. 5 at 146, 189). Finally, Respondent suggests that Petitioner's prior left shoulder injury caused or contributed to the injury at issue. *Id.* 2-3.

VI. Findings of Fact and Dismissal of Table Claim

The above medical records contain preponderant evidence that Petitioner developed left shoulder pain prompting a labral repair in August 2009. This surgery delivered significant relief to Petitioner and he did not require ongoing treatment. However, he was documented to have minor pain and soreness, slightly limited range of motion, and diminished strength in December 2009. He was noted to have only "satisfactory" left shoulder strength in January 2015. Limited complaints of this nature, several years prior to a vaccination, are probative but do not necessarily preclude a finding of onset of new acute shoulder pain consistent with a Table SIRVA.

[14] Petitioner also requested billing records to verify that there was in fact an appointment on September 4, 2018. Brief at 3. at n. 1. Petitioner was indeed billed for the appointment. Ex. 14 at 2.

The more significant issue is that Petitioner himself endorsed left shoulder pain, on hand-written forms, *twice* in the month before his vaccination. He did not dispute the existence of these records, arguing only that the chiropractor's failure to *address* the pain should minimize their significance. That argument is unavailing. Respondent is correct that Petitioner's own handwritten accounts of shoulder pain, created in an effort to seek treatment, are entitled to greater weight than the fact of the treating provider's omission. If petitioners can successfully establish facts relevant to a vaccine injury claim by offering after-the-fact contentions regarding issues that the records are silent on, then their *own* pre-vaccination assertions also should carry evidentiary weight.

Moreover, Petitioner did not distinguish his pain before versus after the vaccination. Indeed, the medical records support Petitioner's later characterization of a "gradual and insidious onset" of left shoulder pain, which he first rated as 4-5/10 on August 22nd; 6/10 on September 4th and 14th; and 8/10 on September 21st. Ex. 2 at 35, 37, 42, 45; Ex. 4 at 11.

I acknowledge that it is often easy for claimants to establish Table onset in SIRVA cases, using their own sworn statements to supplement a thin and non-contradictory record. It is not uncommon for a petitioner to have an unremarkable prior medical history. and for the subsequent medical records to be somewhat lacking in detail with regard to onset. A careful review of the record, supplemented by sworn witness statements, may permit a determination that a petitioner's shoulder pain began within 48 hours after the vaccination. However, not every petitioner can make such a showing, particularly in the face of contemporaneous medical records reflecting his own endorsements of left shoulder pain *before* the vaccination.

VII. Potential for Off-Table Claim

A petitioner's failure to establish a Table injury does not necessarily constitute the end of the case, because he or she might well be able to establish a non-Table claim for either causation-in-fact or significant aggravation. *See Althen v. Sec'y of Health & Human Servs.*, 418 F.3d 1274 (Fed. Cir. 2005); *W.C. v. Sec'y of Health & Human Servs.*, 704 F.3d 1352, 1357 (Fed. Cir. 2013) (citing *Loving v. Sec'y of Health & Human Servs.*, 86 Fed. Cl. 135, 144 (2009)).

Here, Petitioner argues that the flu vaccine caused a "subjectively and objectively distinct" injury, pointing to the new "large rotator cuff tear involving the entire supraspinatus into the infraspinatus [tendons]." Brief at 2-3. Petitioner may be proposing that the flu vaccine caused direct trauma to the rotator cuff. I also recognize that in past cases, certain petitioners have established, via expert testimony, that the flu vaccine can

cause new inflammation and pain in the setting of a preexisting, albeit asymptomatic, rotator cuff tear. *See, e.g.*, *Lesher v. Sec'y of Health & Human Servs.*, No. 17-1076v, 2020 WL 4522381, at *12-13 (Fed. Cl. Spec. Mstr. July 2, 2020); *Sandoval v. Sec'y of Health & Human Servs.*, No. 16-304V, 2019 WL 3820075, at *14-16 (Fed. Cl. Spec. Mstr. July 12, 2019).

Respondent counters that during the December 2018 surgery, Dr. German noted that the biceps anchor placed as part of Petitioner's previous anterior labral repair was unstable and needed further correction. Response at 2. However, Dr. German did not clearly endorse that Petitioner's earlier left shoulder injury caused the new, "massive" rotator cuff tear. He also opined that the rotator cuff tear caused "the lion's share" of Petitioner's problems. Ex. 5 at 148. This issue remains unresolved.

Both parties have presented colorable arguments for Petitioner's worsening shoulder pain in 2018. However, formal resolution of this issue will likely require further review and most likely the retention of experts, which I am not inclined to authorize in the SPU. Moreover, this case has already been pending in the SPU for over nineteen (19) months. To that end, I urge the parties to briefly attempt a litigative risk settlement – as I anticipate that if the case is transferred out of SPU, Petitioner may be able to further develop an off-Table claim (although it may take a significant amount of additional time to do so).

Conclusion

Petitioner has not established the onset of new shoulder pain within 48 hours after the September 11, 2018, flu vaccine. Accordingly, his Table SIRVA claim is dismissed.

It is hereby **ORDERED** that Petitioner shall file a status report confirming that he has conveyed a demand for his off-Table claim[15] **by Thursday, December 16, 2021.** Respondent shall file a status report reporting on the likelihood of a prompt litigative risk settlement in the SPU **by Tuesday, January 17, 2022**.

IT IS SO ORDERED.

s/Brian H. Corcoran
Brian H. Corcoran
Chief Special Master

[15] Petitioner conveyed an initial demand on July 15, 2020. ECF No. 20.